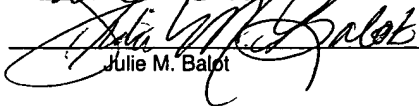




**CERTIFICATE OF MAILING**

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on 28 Jan 2002

  
Julie M. Balot

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

|   |   |
|---|---|
| In re application of: <b>Michael G. Kahn et al.</b>                               | Attorney Docket No.: <b>FSTK 1004-1US</b> |
| Application No.: <b>09/974,781</b>  | Examiner: <b>Unknown</b>                  |
| Confirmation No.: <b>8124</b>   | Group: <b>2166</b>                        |
| Filed: <b>October 10, 2001</b>  | ATTN: Initial Patent Examination Division |
| Title: <b>CLINICAL TRIAL PROTOCOL QUALITY<br/>USING A MODEL-BASED METHODOLOGY</b> |   |

**SUBMISSION OF SUBSTITUTE DRAWINGS UNDER 37 CFR 1.84**

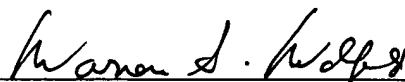
BOX MISSING PARTS  
Commissioner for Patents  
Washington, DC 20231

Sir:

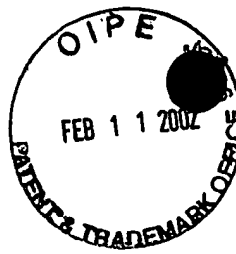
Pursuant to the enclosed Notice to File Missing parts of Nonprovisional Application  
dated October 26, 2001, applicants hereby submit forty-one (41) sheets of substitute drawings.

Respectfully submitted,

Date: 1/28/2002

  
Warren S. Wolfeld, Reg. No. 31,454

HAYNES BEFFEL & WOLFELD LLP  
P.O. Box 366  
Half Moon Bay, California 94019  
Phone: 650-712-0340  
Fax: 650-712-0263



**CERTIFICATE OF MAILING**

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail to: Box Missing Parts, Commissioner for Patents, Washington, DC 20231 on 2002 January 10, 2002.

*Julie M. Balot*  
Julie M. Balot

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

|   |   |
|---|---|
| In re application of: <b>Michael G. Kahn et al.</b>                           | Attorney Docket No.: <b>FSTK 1004-1US</b> |
| Application No.: <b>09/974,781</b>  | Examiner: <b>Unknown</b>                  |
| Confirmation No.: <b>8124</b>   | Group: <b>2166</b>                        |
| Filed: <b>October 10, 2001</b>  |   |
| Title: <b>CLINICAL TRIAL PROTOCOL QUALITY USING A MODEL-BASED METHODOLOGY</b> |   |

**RESPONSE TO NOTICE OF MISSING PARTS OF APPLICATION**

BOX MISSING PARTS  
Commissioner for Patents  
Washington, DC 20231

Sir:

In response to the Notice to File Missing Parts of Application dated May 16, 2001, enclosed please find:

- ☒ Form PTO-1533 (copy of Notice to be returned with response);
- ☒ Three Declarations for Utility Patent Application signed by inventors;
- ☒ Three Assignments signed by Inventor with Form PTO-1595;
- ☒ Three Power of Attorney or Authorization of Agent forms signed by inventors;
- ☒ A Power of Attorney or Authorization of Agent forms signed by Michael G. Kahn in his capacity as Vice President of FastTrack Systems, Inc.;
- ☒ Statement Under 37 CFR 3.37(b) with copies of executed Assignments;
- ☒ Submission of Substitute Drawings Under 37 CFR 1.84 along with 41 sheets of substitute drawings;
- ☒ Preliminary Amendment;
- ☒ Information Disclosure Statement;
- ☒ Two pages of Form 1449 and copies of twelve (12) citations.;
- ☒ Supplemental Application Data Sheet;
- ☒ Petition for Extension of Time (one month);
- ☒ Fee Transmittal for FY 2002; and
- ☒ Check No. 1620 in the amount of \$893.00.

2011-01-10 10:20:20

The Commissioner is hereby authorized to charge any additional fees that may be required and to credit any overpayment, to Deposit Account No. 50-0869 (Docket No. FSTK 1004-1US). A duplicate of this paper is enclosed.

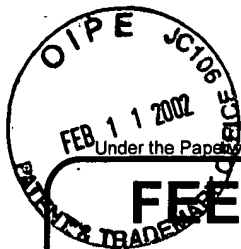
Respectfully submitted,

Date: 1/28/2002

Warren S. Wolfeld  
Warren S. Wolfeld, Reg. No. 31,454

HAYNES BEFFEL & WOLFELD LLP  
P.O. Box 366  
Half Moon Bay, California 94019  
Phone: 650-712-0340  
Fax: 650-712-0263

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PTO/SB/17 (10-01)  
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Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

# FEE TRANSMITTAL for FY 2002

Patent fees are subject to annual revision.

TOTAL AMOUNT OF PAYMENT (\$) 893.00

## Complete if Known

|                      |                 |
|----------------------|-----------------|
| Application Number   | 09/974,781      |
| Filing Date          | 10/10/2001      |
| First Named Inventor | Michael G. Kahn |
| Examiner Name        | Unknown         |
| Group Art Unit       | 2166            |
| Attorney Docket No.  | FSTK 1004-1US   |

## METHOD OF PAYMENT

1. ☐ The Commissioner is hereby authorized to charge indicated fees and credit any overpayments to:

Deposit Account Number 50-0869

Deposit Account Name Haynes Beffel & Wolfeld LLP

☒ Charge Any Additional Fee Required Under 37 CFR 1.16 and 1.17

☒ Applicant claims small entity status. See 37 CFR 1.27

2. ☒ Payment Enclosed:

☒ Check ☐ Credit card ☐ Money Order ☐ Other

## FEE CALCULATION

### 1. BASIC FILING FEE

| Large Entity Fee Code (\$) | Small Entity Fee Code (\$) | Fee Description        | Fee Paid |
|----------------------------|----------------------------|------------------------|----------|
| 101 740                    | 201 370                    | Utility filing fee     | 370.00   |
| 106 330                    | 206 165                    | Design filing fee      |          |
| 107 510                    | 207 255                    | Plant filing fee       |          |
| 108 740                    | 208 370                    | Reissue filing fee     |          |
| 114 160                    | 214 80                     | Provisional filing fee |          |

SUBTOTAL (1) (\$) 370.00

### 2. EXTRA CLAIM FEES

| Total Claims       | Extra Claims | Fee from below | Fee Paid |
|--------------------|--------------|----------------|----------|
| 51                 | -20** = 31   | 9.00           | 279.00   |
| 5                  | -3** = 2     | 42.00          | 84.00    |
| Multiple Dependent |              |                |          |

| Large Entity Fee Code (\$) | Small Entity Fee Code (\$) | Fee Description  |
|----------------------------|----------------------------|--|
| 103 18                     | 203 9                      | Claims in excess of 20                                     |
| 102 84                     | 202 42                     | Independent claims in excess of 3                          |
| 104 280                    | 204 140                    | Multiple dependent claim, if not paid                      |
| 109 84                     | 209 42                     | ** Reissue independent claims over original patent         |
| 110 18                     | 210 9                      | ** Reissue claims in excess of 20 and over original patent |

SUBTOTAL (2) (\$) 363.00

\*\*or number previously paid, if greater, For Reissues, see above

## FEE CALCULATION (continued)

### 3. ADDITIONAL FEES

| Large Entity Fee Code (\$) | Small Entity Fee Code (\$) | Fee Description  | Fee Paid |
|----------------------------|----------------------------|--|----------|
| 105 130                    | 205 65                     | Surcharge - late filing fee or oath  | 65.00    |
| 127 50                     | 227 25                     | Surcharge - late provisional filing fee or cover sheet                     |          |
| 139 130                    | 139 130                    | Non-English specification  |          |
| 147 2,520                  | 147 2,520                  | For filing a request for <i>ex parte</i> reexamination                     |          |
| 112 920*                   | 112 920*                   | Requesting publication of SIR prior to Examiner action                     |          |
| 113 1,840*                 | 113 1,840*                 | Requesting publication of SIR after Examiner action                        |          |
| 115 110                    | 215 55                     | Extension for reply within first month                                     | 55.00    |
| 116 400                    | 216 200                    | Extension for reply within second month                                    |          |
| 117 920                    | 217 460                    | Extension for reply within third month                                     |          |
| 118 1,440                  | 218 720                    | Extension for reply within fourth month                                    |          |
| 128 1,960                  | 228 980                    | Extension for reply within fifth month                                     |          |
| 119 320                    | 219 160                    | Notice of Appeal   |          |
| 120 320                    | 220 160                    | Filing a brief in support of an appeal                                     |          |
| 121 280                    | 221 140                    | Request for oral hearing   |          |
| 138 1,510                  | 138 1,510                  | Petition to institute a public use proceeding                              |          |
| 140 110                    | 240 55                     | Petition to revive - unavoidable   |          |
| 141 1,280                  | 241 640                    | Petition to revive - unintentional   |          |
| 142 1,280                  | 242 640                    | Utility issue fee (or reissue)   |          |
| 143 460                    | 243 230                    | Design issue fee   |          |
| 144 620                    | 244 310                    | Plant issue fee  |          |
| 122 130                    | 122 130                    | Petitions to the Commissioner  |          |
| 123 50                     | 123 50                     | Processing fee under 37 CFR 1.17(q)  |          |
| 126 180                    | 126 180                    | Submission of Information Disclosure Stmt                                  |          |
| 581 40                     | 581 40                     | Recording each patent assignment per property (times number of properties) | 40.00    |
| 146 740                    | 246 370                    | Filing a submission after final rejection (37 CFR § 1.129(a))              |          |
| 149 740                    | 249 370                    | For each additional invention to be examined (37 CFR § 1.129(b))           |          |
| 179 740                    | 279 370                    | Request for Continued Examination (RCE)                                    |          |
| 169 900                    | 169 900                    | Request for expedited examination of a design application                  |          |

Other fee (specify) \_\_\_\_\_

\*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) (\$) 160.00

## SUBMITTED BY

Name (Print/Type) Warren S. Wolfeld

Registration No. 31,454  
(Attorney/Agent)

## Complete (if applicable)

Telephone (650) 712-0340

Signature

*Warren S. Wolfeld*

Date 1/28/2002

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

Burden Hour Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.



## UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS  
UNITED STATES PATENT AND TRADEMARK OFFICE  
WASHINGTON, D.C. 20231  
www.uspto.gov

| APPLICATION NUMBER | FILING/RECEIPT DATE | FIRST NAMED APPLICANT | ATTORNEY DOCKET NUMBER |
|--------------------|---------------------|-----------------------|------------------------|
| 09/974,781         | 10/10/2001          | Michael G. Kahn       | FSTK 1004-1            |

CONFIRMATION NO. 8124

22470  
HAYNES BEFFEL & WOLFELD LLP  
P O BOX 366  
HALF MOON BAY, CA 94019

## FORMALITIES LETTER



\*OC000000006981383\*

Date Mailed: 10/26/2001

## NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

FILED UNDER 37 CFR 1.53(b)

*Filing Date Granted*

An application number and filing date have been accorded to this application. The item(s) indicated below, however, are missing. Applicant is given **TWO MONTHS** from the date of this Notice within which to file all required items and pay any fees required below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

- The statutory basic filing fee is missing.  
*Applicant must submit \$ 370 to complete the basic filing fee for a small entity.*
- Total additional claim fee(s) for this application is \$363.
  - \$279 for 31 total claims over 20.
  - \$84 for 2 independent claims over 3.
- The oath or declaration is missing.  
*A properly signed oath or declaration in compliance with 37 CFR 1.63, identifying the application by the above Application Number and Filing Date, is required.*
- To avoid abandonment, a late filing fee or oath or declaration surcharge as set forth in 37 CFR 1.16(l) of \$65 for a small entity in compliance with 37 CFR 1.27, must be submitted with the missing items identified in this letter.
- The balance due by applicant is \$ 798.**

The application is informal since it does not comply with the regulations for the reason(s) indicated below.

The required item(s) identified below must be timely submitted to avoid abandonment:


- Substitute drawings in compliance with 37 CFR 1.84 because:
  - drawing sheets do not have the appropriate margin(s) (see 37 CFR 1.84(g)). Each sheet must include a top margin of at least 2.5 cm. (1 inch), a left side margin of at least 2.5 cm. (1 inch), a right side margin of at least 1.5 cm. ( 5/8 inch), and a bottom margin of at least 1.0 cm. (3/8 inch);

02/14/2002 BNGUYEN1 00000017 09974781

|           |           |
|-----------|-----------|
| 01 FC:201 | 370.00 OP |
| 02 FC:203 | 279.00 OP |
| 03 FC:202 | 84.00 OP  |
| 04 FC:205 | 65.00 OP  |

09974781-1024102

*A copy of this notice **MUST** be returned with the reply.*



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Customer Service Center

Initial Patent Examination Division (703) 308-1202

PART 2 - COPY TO BE RETURNED WITH RESPONSE

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